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PETITIONS OFFICE

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Total # of Pages 10 (including this page)

TO:	PHONE:	FAX #:
Ms. Karin Tyson U.S. Patent & Trademark Office	(703) 306 3159	(703) 872 9411 (703) 308 6916

In re Interim Patent Term Extension of U.S. Patent No. 4,373,527

Patentee: Robert E. Fischell

Assignee: The Johns Hopkins University

Issue Date: February 15, 1983

From: Maggie K. McDevitt

Sender's Direct Dial: (202) 672 5304

Date: September 7, 2001

Client/Matter No: 047711/0100

MESSAGE:

Attached is a copy of the Second Year Request for Interim Extension of Patent Term and the date-stamped postcard. Please note that Check No. 9224 for \$220.00 cleared our account on January 17, 2001.

If there are any problems with this transmission or if you have not received all of the pages, please call (202) 672-5304.

Operator:	Time Sent:	Return Original To:
		Maggie K. McDevitt

CONFIDENTIALITY NOTICE: THE INFORMATION CONTAINED IN THIS FACSIMILE MESSAGE IS INTENDED ONLY FOR THE PERSONAL AND CONFIDENTIAL USE OF THE DESIGNATED RECIPIENTS NAMED ABOVE. THIS MESSAGE MAY BE AN ATTORNEY-CLIENT COMMUNICATION, AND AS SUCH IS PRIVILEGED AND CONFIDENTIAL. IF THE READER OF THIS MESSAGE IS NOT THE INTENDED RECIPIENT OR ANY AGENT RESPONSIBLE FOR DELIVERING IT TO THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT YOU HAVE RECEIVED THIS DOCUMENT IN ERROR, AND THAT ANY REVIEW, DISSEMINATION, DISTRIBUTION OR COPYING OF THIS MESSAGE IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE NOTIFY US IMMEDIATELY BY TELEPHONE AND RETURN THE ORIGINAL MESSAGE TO US BY MAIL. THANK YOU.

Cover Page 1 of 1

Docket No. 047711/0100

Receipt is hereby acknowledged of the following:

Assignee: The John Hopkins University
U.S. Patent No.: 4,373,527
Issue Date: February 15, 1983

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PETITIONS OFFICE

1. Check No. 9224 for \$220
2. Second Year Request for Interim Extension of Patent Term Under 35 U.S.C. § 156(d)(5) in duplicate

Date Due: January 12, 2001
Date: January 12, 2001

Return to: SBM/mkm
Inspected by: JFM



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BOX PATENT EXT.

PETITIONS OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket No. 047711/0100

In re: U.S. Patent No. 4,373,527

Patentee: Robert E. FISCHELL

Assignee: The Johns Hopkins University

Issue Date: February 15, 1983

SECOND YEAR REQUEST FOR *INTERIM* EXTENSION OF PATENT TERM
UNDER 35 U.S.C. § 156(d)(5)

Commissioner of Patents and Trademarks
Washington, D.C. 20231
BOX PATENT EXT.

Sir:

On January 28, 2000, The Johns Hopkins University ("Hopkins") timely filed an interim patent term extension application for the above U.S. Patent No. 4,373,527 ("the '527 patent"). The '527 patent was originally due to expire on Feb. 15, 2000, but with a one-year interim extension, it will expire on Feb. 15, 2001. On Feb. 7, 2000, the Patent Office sent a communication denying the one-year interim extension but permitting Hopkins an opportunity to request reconsideration. On March 27, 2000, following an interview between the undersigned and Ms. Karin Tyson of the Patent Office, Ms. Tyson sent a letter to the FDA stating that the '527 patent would be eligible for an extension "only if an application under section 515 of [the Act] was initially submitted prior to January 28, 2000 for the product Minimed 2007." Hopkins followed up the interview with a formal Request for Reconsideration, which was filed on May 8,

2000. To date, the FDA has not responded to Ms. Tyson's March 27, 2000 letter, and so the Patent Office has been unable to respond to Hopkins' Request for Reconsideration.

37 C.F.R. 1.790(a) specifies that a patentee must file a second or subsequent interim extension application during the period beginning 60 days before and ending 30 days before the expiration of the preceding interim extension. Because that deadline is approaching and because Hopkins has yet to receive a final decision on its first-year interim extension, Hopkins herewith submits its second-year interim extension application and requests the PTO to grant a second-year interim extension for the '527 patent. The '527 patent is entitled to a second year interim extension because the FDA has not yet approved Minimed 2007 and there was an application under section 515 of [the Act] for the Minimed 2007 initially submitted prior to January 28, 2000, as explained in Hopkins' May 8, 2000 Request for Reconsideration.

The information required by 37 C.F.R. 1.790(c) is submitted in the following sections and in the attachments to this application.

STATEMENT THAT REGULATORY REVIEW PERIOD HAS NOT BEEN COMPLETED

As of the date of filing this application, the regulatory review period for Minimed 2007 has not been completed.

**ITEMS REQUIRED BY 37 C.F.R. §§ 1.740 & 1.790 NOT SUBMITTED WITH FIRST
INTERIM EXTENSION APPLICATION**

The following information is submitted in accordance with 35 U.S.C. § 156(d) and 37 C.F.R. § 1.740, and follows the format and requirements set forth in 37 C.F.R. § 1.740.

“A brief description beginning on a new page of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities” 37 C.F.R. § 1.740(a)(11).

Application for Second-Year *Interim* Patent Term Extension
US Patent No. 4,373,527

Attached is a chronology that briefly describes the significant regulatory activities associated with Minimed 2007 since the last date on the list provided with the first interim extension application (Exhibit 1).

"The prescribed fee for receiving and acting upon the application for extension," 37 C.F.R. § 1.740(a)(14).

Pursuant to 37 C.F.R. § 1.20(j)(3), a check in the amount of \$ 220.00 is enclosed with this application.

"The name, address and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed," 37 C.F.R. § 1.740(a)(15).

Please direct all inquires and correspondence relating to this application for patent term extension to:

Stephen B. Maebius
Foley & Lardner
3000 K Street, N.W.
Washington, DC 20007
202-672-5569

"A duplicate of the application papers, certified as such," 37 C.F.R. § 1.740(a)(16).

Enclosed is a certification that this application for patent extension, including its attachments, is being submitted as one original and one duplicate copy thereof (Exhibit 2).

Application for Second-Year *Interim* Patent Term Extension
US Patent No. 4,373,527

"An oath or Declaration as set forth in 37 C.F.R. § 1.740(b)," 37 C.F.R. § 1.740(a)(ii).

The requisite declaration pursuant to 37 C.F.R. § 1.740(b) is attached as Exhibit 3.

Respectfully submitted,

January 12, 2001


Stephen B. Maebius
Reg. No. 35,264

FOLEY & LARDNER
3000 K Street, N.W.
Suite 500
Washington, D.C. 20007-5109
Tel: (202) 672-5569
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Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.

FROM : FOLEY & LARDNER

FAX NO. : 202-945-6173

Sep. 07 2001 11:29AM P7

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<< Interrupted Transmission >>